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EXAMINER				
SEHARASEYON, JEGATHEESAN				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/001,367

**Applicant(s)**

BREWITT, BARBARA A.

**Examiner**

Jegatheesan Seharaseyon, Ph.D

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2007 and 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 13-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 1, 13-28 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This office action is in response to the amendments and remarks filed on 9/11/2007 and 9/26/2007. Claims 1, 2, 11, 13-28 and 30-33 are currently pending and are examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

#### ***Claim Rejections - 35 USC § 102(b) maintained***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 11, and 14 under 35 USC § 102(b) as being anticipated over Antoniadis et al. is maintained for reasons set forth in the Office Actions dated 8/24/04, 6/13/05, 6/27/2006 and 2/22/07.

Applicant indicates that the composition of Antoniadis et al. is directed to wound healing. Applicant argues that use of homeopathic potency of IGF-1 is not taught by Antoniadis et al. Applicant contends that the homeopathic compositions of the instant invention are highly dilute preparations and it is the preparatory process, and not merely the highly dilute nature of the preparation, that renders a preparation a homeopathic potency. Specifically, Applicant is arguing that there is no teaching or suggestion whatsoever in Antoniadis et al. that the compositions are prepared homeopathically to produce homeopathic potencies. It is argued that there is no description, either

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expressly or inherently, of homeopathic potencies, or of serial dilutions and serial successions. In addition, Applicant is arguing that no homeopathic nomenclature is used. Applicant asserts that the molar concentration of homeopathic preparations is not an important or characterizing feature of the homeopathic preparations. Rather it is asserted that, it is the energetic properties imparted to the preparations as a result of the specialized and standardized techniques of preparing homeopathic potencies, involving both serial dilutions and serial successions, which characterize and define homeopathic potencies (Applicant is claiming the product by the process). Further, Applicant contends that even if the molar concentration of applicant's homeopathic preparations were substantially the same as those disclosed by Antoniades et al., a homeopathic preparation is different and distinct from a pharmaceutically prepared composition and there is no anticipation.

Applicant's arguments have been fully considered but are not found to be persuasive because in the absence of a disclosure of a particular starting concentration of IGF-1 in claim 1 it is anticipated that the concentration disclosed by Antoniades et al. (IGF-1 of 500ng-1  $\mu$ g) is included in the instant invention, regardless of the method used to prepare IGF-1 composition of the instant invention (The various homeopathic potencies could potentially include the concentration of IGF-1 disclosed in the instant invention). Although, Applicant asserts that energetic properties are imparted to the preparations as a result of the specialized and standardized techniques of preparing homeopathic potencies, the claims do not recite that the preparations contain any energetic properties to differentiate over the prior art. In addition, arguments relating to

method of making were previously addressed in the Office Action dated of 6/27/2006 (pages 3-5), which have not been responded to by the Applicant in the instant response and the previous response (11/27/2006).

It is also noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276,

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279, 162 USPQ 221, 223 (CCPA 1979) (holding “interbonded by interfusion” to limit structure of the claimed composite and noting that terms such as “welded,” “intermixed,” “ground in place,” “press fitted,” and “etched” are capable of construction as structural limitations.) Likewise homeopathic potency does not distinguish the prior art over the instant invention.

In addition, Applicant has not provided any evidence to indicate that there is an unobvious difference between the product of prior art and that of the instant invention because composition of IGF-1 containing 500ng-1  $\mu$ g taught by Antoniades et al. For example, there is no evidence to indicate that “energetic properties” have been imparted by the —reparation methods. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be “essentially free of alkali metal.” The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not “essentially free of alkali metal” and therefore a different and unobvious product.).

Additionally, *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.). Therefore, the rejection of record is maintained.

***Claim Rejections - 35 USC § 112, first paragraph, maintained***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 2 11, 13-28 and 30-33 under 35 USC § 112, first paragraph as failing to comply with enablement requirement is maintained for reasons set forth in the Office Action dated 2/22/07.

Applicant is asserting that the Office is treating the claimed preparation as allopathically prepared pharmaceutical preparation. Applicant has provided an excerpt from the Homeopathic Pharmacopoeia of the United States (Exhibit A) in an attempt to

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show the preparation of homeopathic preparations. Applicant also contends that Homeopathic Pharmacopoeia has been published since 1897 and provides straightforward explanation of the preparation of homeopathic potencies. Applicant further accepts that there is no reference to molar concentrations of starting material provided in the reference and argues that the molar concentration is not relevant to the homeopathic potency. Applicant further asserts that the specification and the knowledge in the art provide sufficient guidance to one of ordinary skill in the art to make the claimed preparations. It is asserted that homeopathy is an ideal therapeutic medium for self-medication of symptoms usually associated with self-limiting conditions since the selection of the proper remedy for the case is dependent on the symptoms that the body exhibits in its reaction to the illness.

It is further argued that substantial commercial sales of preparations comprising homeopathic potencies of purified IGF-1 have taken place in the past several years. Applicant asserts that consumer users are well skilled in the art of using homeopathic preparations and homeopathic practitioners are well skilled in the art of prescribing homeopathic preparations. Further, Applicant claims that their use is not governed by pathologies or by mechanisms of action but, rather, by the effect(s) it produces. Thus, it is claimed that the preparations is well within the skill of both homeopathic practitioners and consumer users.

Applicant's arguments have been fully considered but are not found to be persuasive because as indicated above there is no reference to concentrations of starting material provided in the reference or specification. Thus, in the absence of



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adequate guidance provided in the specification and the prior art of record with respect to starting concentrations of IGF-1 it would require undue amount of experimentation for one skilled in the art to practice the claimed invention of preparing a composition with homeopathic potency, specially given the physiological concentration of IGF-1 is 200ng/ml. Although, Applicant claims that homeopathic preparations are ideal for self medication, there is no guidance provided for the preparation of such. In addition, symptomatic treatment would require trial error experimentation to identify the illness and the dosage required to alleviate the symptoms. Although, Applicant claims that substantial commercial sales of preparations comprising homeopathic potencies of purified IGF-1 have taken place in the past several years, there is no guidance with respect to starting material provided. Further, the Applicant asserts that the consumer users are skilled in the art of using homeopathic preparations yet provides no example. There is no teaching which provides for one to correlate the homeopathic preparations with symptoms to be treated. Although, Applicant claims that their use is not governed by pathologies or by mechanisms of action but, rather, by the effect(s) it produces but no examples are provided and in the absence of such teaching it would require trial and error experimentation.

Further Applicant has not addressed the lack of teaching provided for variables such as biological stability, half-life or clearance from the blood etc. for the homeopathic preparation of the instant invention. Applicant has also not responded to the lack of teaching in the specification with respect to the oral administration as discussed in

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pages 5-6 of the previous Office Action dated 2/22/2007. Therefore, the enablement rejection of record is maintained.

5. New Claim rejections added.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 1, 2, 11, 13-28 and 30-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-14, 16 and 19 of U.S. Patent No. 6,239,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully-disclosed in the in the cited patent claims.

6b. Claims 1, 2, 11-28, 30-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4-20 of copending Application No. 11/242, 988. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully-disclosed in the in the cited application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

7. No claims are allowable.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS

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December 18<sup>th</sup>, 2007

/Jegatheesan Seharaseyon, Ph.D./

Primary Examiner, Art Unit 1647